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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,753	08/31/2000	Sonti Venkata Ramakrishna	U 012932-5	3517

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Ladas & Parry
26 West 61st Street
New York, NY 10023

EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/652,753	Applicant(s) RAMAKRISHNA ET AL.	
	Examiner Kartic Padmanabhan	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/17/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 22-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 and 22-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/04 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 20, 22-28, and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146) in view of Yuan (US Pat. 6,153,416).

Ramakrishna et al. teach a process for the preparation of stable yeast crystals. According to the invention, yeast is grown by inoculation in media that was sterilized at 121 degrees Celsius after the pH had been adjusted to 6.8-7.2 using 1 N sodium chloride or 1 N hydrochloric acid. This was then incubated on a shaker at 26-30 degrees Celsius for about 24 hours with aeration. The yeast was then separated by centrifugation at 5,000-15,000 rpm for 10 minutes at 24-32 degrees Celsius. A yeast slurry was then prepared by mixing the yeast 0.5-10% with 0.5-3% natural polymer solution. The immobilized yeast beads were then prepared by adding this solution dropwise into a curing solution of 0.05-0.3 M calcium chloride solution. The beads were kept in this solution overnight at a temperature of 4 degrees Celsius. The immobilized yeast beads were then separated by decanting the solution and washed with distilled water several times. The beads were then dehydrated at a temperature of 24-36 degrees Celsius for 2-20 hours to obtain stable yeast crystals having a moisture content of 5-30%. These crystals were activated by incubation in 5-8% molasses solution for 2-48 hours at 24-32 degrees Celsius. The yeast crystals were then separated by draining this aqueous solution (Col. 4, lines 8-53). Sodium alginate 2% was generally used in preparing the yeast slurry (Col. 4, lines 64). However, the reference does not teach selecting a culture from activated sludge.

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Yuan teaches the immobilization of microbial cells in polymeric beads. The process of the reference can be used effectively to immobilize yeast, as well as activated sludge microorganisms and waste water treatment microorganisms (Col. 2, line 63 – Col. 3, line 5).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the microbial consortia obtained from wastewater treatment plants as taught by Yuan with the method of Ramakrishna et al. because Yuan teaches that both yeast and waste water microorganisms can be used for immobilization onto beads. Therefore, one could have substituted wastewater microorganisms for the yeast in Ramakrishna et al. with a reasonable expectation of success. It would also have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the specific media of the pending claims, as well as an aeration of 5 ml/minute and glucose as activation solution. The selection of these parameters merely represents an optimization of the assay protocol and do not patentably distinguish the claimed invention over the prior art of record. One of skill in the art would easily be capable of selecting parameters, such as media and aeration rate that promote yeast growth. In addition, one could have also substituted glucose solution for the molasses solution of the reference with a reasonable expectation that the same intended result would be achieved, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Further, the reference discloses the use of 1 N solutions to adjust pH, as opposed to 0.1 N as claimed. However, it would have been obvious to use 0.1 N solutions with the invention of the reference because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In this case, the use of a less concentrated solution allows for the concentration of

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the media to be adjusted at a more gradual rate than if using a more concentrated solution, with the selection of the preferred concentration well within the skill of those in the art.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146) in view of Yuan (US Pat. 6,153,416) as applied to claims 20, 22-28, and 30-36 above, and further in view of Husain et al. (US Pat. 6,361,695).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the reference does not teach the termination of growth at an MLSS of 14,500-15,500 mg/liter.

Husain et al. teach a wastewater treatment system wherein when the MLSS reaches levels of 15 g/l (15,000 mg/liter), some of the mixed liquor is removed from the bioreactor. The MLSS levels must be below this level for effective effluent treatment.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the MLSS levels of Husain et al. with the modified method of Ramakrishna et al. and Yuan because after an MLSS of 15,000 mg/liter has been reached, optimal conditions for effluent treatment and growth of microbes no longer exist.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 20, 22-28, and 30-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan (US Pat. 6,153,416). Although the conflicting claims are not identical, they are not patentably distinct from each other because the steps involved in the method of the present application and of the claims in the '146 patent are very similar in scope, thus rendering the claims not patentably distinct. The '146 patent fails to teach the selection of microbial consortia from wastewater treatment plants or activated sludge, a deficiency that is remedied by Yuan. For detailed reasons of the similarities between the claims, applicant is directed to the rejection over Ramakrishna et al. in view of Yuan under 35 USC 103. Although the rejections does not specifically address the claims in the '146 patent, the claims closely resemble the part of the disclosure applied in the rejections.

9. Claim 29 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan (US Pat. 6,153,416) as applied to claims 20, 22-28, and 30-36 above, and further in view of Husain et al. (US Pat. 6,361,695). The '146 patent and Yuan teach the basic method of the claimed invention, as discussed above, but fail to teach the specific range of MLSS of the

claimed invention, a deficiency that is remedied by Husain et al., as discussed under 35 USC 103.

Response to Arguments

10. Applicant's arguments filed June 17, 2004 have been fully considered but they are not persuasive.

11. Applicant's arguments that the combination of Ramakrishna et al. and Yuan et al. is improper because Yuan teaches away from the invention are not convincing. Although Yuan may indeed state that natural immobilization techniques may provide less than optimal results, the reference does not state that these techniques would not work. Although they contemplate the use of other immobilization techniques, the reference does not rule out the use of natural techniques. The reference states that natural polymers have achieved some success in the industrial application, and goes on to provide the method of natural immobilization. Further, it is noted that Yuan, as a secondary reference, is *only* relied upon for the teaching of selecting a culture from activated sludge, as the immobilization technique of the present invention is already taught by Ramakrishna et al. as the primary reference. Contrary to applicant's assertion, one would not have to disbelieve the teaching in Yuan to arrive at the claimed invention because Yuan states that natural polymer immobilization techniques work.

12. In response to applicant's argument that Yuan does not teach culturing of organisms as set out in claim 20, the examiner agrees; however, the primary reference teaches the method of culturing, and Yuan, as a secondary reference is only relied upon for the source of the consortia. In addition, although there is nothing in the references that suggest yeast would be waste water treatment microorganisms, since Yuan teaches the immobilization of yeast and activated sludge microorganisms and waste water treatment microorganisms, one would have had a reasonable

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expectation of success in substituting the microorganisms of Yuan with the yeast of Ramakrishna et al. and still achieving immobilization onto the beads.

13. Applicant's arguments regarding the obviousness type double patenting rejection are unconvincing for reasons discussed above in reference to the prior art rejections.

Conclusion

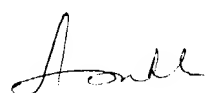
Claims 20 and 22-36 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



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07/05/04